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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,451	10/09/2001	Myron K. Jacobson	NIAD-201.3 DIV - AP/NDH	7369

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EXAMINER
LACOURCIERE, KAREN A

ART UNIT	PAPER NUMBER
1635	10

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No.	Applicant(s)	
	09/973,451	JACOBSON ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-39 and 41-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *36-39 and 41-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 36-39, 44-46 and 51-54, drawn to a method of treating, preventing or ameliorating a disease using a PARG modulator, classifiable in class 514, subclass 44.

II. Claims 41 and 42, drawn to a method of identifying a mutant PARG allele in an individual, classifiable in class 435, subclass 6.

III. Claim 43, drawn to a method of screening molecules for PARG modulating activity, classifiable in class 435, subclass 6.

IV. Claims 47-50, drawn to a method of sensitizing a cell to a chemotherapeutic agent using an agent that modulates an enzymatic activity of a PARG enzyme, classifiable in class 514, subclass 2.

V. Claims 55-58, drawn to an antibody to a PARG enzyme, classified in class 530, subclass 387.1.

VI. Claims 59-61, drawn to a pharmaceutical composition comprising a nucleic acid molecule targeted to a PARG enzyme, classified in class 536, subclass 24.5.

VII. Claims 62-64, drawn to a transgenic mouse with a PARG endogenous gene knockout, classified in class 800, subclass 8.

VIII. Claims 65 and 66, drawn to a nucleic acid encoding a PARG enzyme, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Each of the Inventions of Groups I and II and III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods with different method steps and different functions, modes of operation and effects. For example, the methods of Group I have the effect of treating, preventing or ameliorating a disease in a subject, which is distinct from the effects of each of the methods of Group II and III and IV, which have the effect of identifying a mutant allele in a subject, determining if a molecule is capable of modulating a PARG enzyme activity and sensitizing a cell to a chemotherapeutic, respectively. Each of these effects are distinct from the effects of the methods of Group I and, further, each effect of Groups II and III and IV are distinct from one another and, therefore, each of Groups I and II and III and IV is drawn to a distinct and unrelated invention.,

Each of the Inventions of Groups I and II and III and IV and each of the Inventions of Groups V, VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, each of the compositions of Groups V and VI and VII and VIII may be useful in a method of treatment of Group I, identifying a mutant allele of Group II, screeing for modulators of Group III, or sensitizing a cell of Group IV, however, each of these

compositions can be used in materially different methods than that of the methods of Group I or II or III or IV and the each of the methods of Group I or II or III or IV can be practiced with materially different compositions (or practiced with a subject different than that of Group VII) than each of the compositions of Groups V and VI and VII and VIII. For example, the antibody of Group V can be used to measure levels of a PARG enzyme in a diagnostic assay, the nucleic acid molecule targeting a PARG encoding polynucleotide can be used in an in vitro system to test PARG activities in a cell or to make an animal PARG depleted disease model, the nucleic acid encoding PARG can be used for overexpression of PARG in a method of purification and the transgenic mouse of Group VII can be used in a method of screening for modulators of PARG or for testing a treatment method. Each of these methods if materially different than the methods Groups I and II and III and IV and, therefore, Groups V and VI and VII and VIII are drawn to inventions distinct from that of each of Groups I and II and III and IV.

Each of the Inventions of Groups V and VI and VII and VIII are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different compositions with different modes of operation and functions. For example, the antibody of Group V operates by binding directly to a PARG enzyme and inhibiting its function and is composed of amino acids, whereas the nucleic acid of Group VI is composed of nucleotides and operates by hybridizing to a nucleic acid encoding PARG and inhibiting its expression and the transgenic mouse is composed of organs and functions to provide an animal model for disease wherein a PARG enzyme is knocked out and the nucleic acid encoding PARG

is composed of nucleotides and functions by expressing a PARG enzyme. Each of these compositions is distinct from the invention of Group V and from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper and the search required for each Group is distinct, restriction for examination purposes as indicated is proper.

Further Restriction to ONE Sequence for each of Groups I and VIII

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in claim 44, 65 and 66 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434), however, due to the heavy search burden placed on the Office, an election of one single sequence is required if Applicant should elect Group I or VII.

Groups I and VII, in claims 44, 65 and 66 are specifically drawn to SEQ ID NOS 1, 3, 5, 7 and 9, or a nucleic acid encoding SEQ ID NO: 2, 4, 6, 8 and 10. Applicant is required to elect one of these sequences. The sequences are considered to be unrelated, since each sequence claimed is structurally independent and distinct. Furthermore, a search of more than one (1) of the sequences claimed in claim 44, 65 and 66 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of

more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination.

Applicant is further notified that upon election of any of Groups II-VI, if during prosecution the claims are amended to read on specific distinct and separate sequences, such that the claims result in being drawn to multiple inventions, Applicant may be required to elect one sequence for the elected invention in any of Groups II-VI

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
September 25, 2003